

ISN Programs

Clinical Research Program

Practical Details for Applicants.
2018 edition

<http://cr.theisn.org>

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Types of Studies Funded by the Program

Four types of studies are funded by the Clinical Research Program:

1. Screening and intervention studies

These studies identify individuals at high risk for or with chronic kidney disease through screening programs. They should be complemented by patient follow-up programs focusing on medical management including health education, lifestyle modification and pharmacological treatment in order to reduce end-stage kidney and cardiovascular disease and mortality.

2. Clinical research studies addressing specific local needs

These clinical research projects address specific needs at the local regional/country level. Projects should be related to acute or chronic kidney disease.

3. Acute kidney injury studies

Projects that focus on clinical aspects of Acute Kidney Injury (AKI) in low and middle income countries – especially studies on epidemiology, risk factors, prevention and treatment and that align with key priorities of the 0by25 ISN human rights initiative.

4. Chronic kidney disease studies

CKD of unknown origin (CKDu): Projects that focus on clinical aspects of CKDu in low and middle income countries – especially studies on epidemiology, risk factors, prevention and treatment and that align with key priorities of the ISN work to tackle the global CKDu situation.

Application Deadlines

APRIL 1st: Proposals to be sent to regional coordinators

MAY 1st: Online submission of finalized application

SEPTEMBER 1st: Proposals to be sent to regional coordinators

OCTOBER 1st: Online submission of finalized application

There are two rounds each year for online submission of the proposals with the following deadlines (at 10 p.m., Central Europe Time): **May 1st and October 1st**. These are the dates that your fully finalized application must be submitted using the online submission site.

However, you first need to obtain a letter of approval from your relevant Regional Coordinator who reviews your proposal and provides feedback to ensure it is adequate for submission. In order to ensure a timely review, the proposals need to be sent to the Coordinator no later than **1 month before** of the final submission deadline. More information about this is provided further below under Application Steps and Procedures.

Eligibility Criteria

There are several eligibility criteria for applicants to consider. These include:

Project Criteria:

- The project must be conducted in a low- or middle-income country (LMIC). This classification is based on World Bank ranking. Priority will be given to countries that are the least developed but have a reasonable infrastructure to allow the implementation of the project.
- The project should be complementary to, or in alignment with, the national or institutional health strategy or mission and correspond to one of the three types of fundable projects as mentioned above.
- Applications addressing specific local needs must be accompanied by a letter of support from the Regional Coordinator to confirm the regional need.
- The project must be feasible within the time and budget proposed.
- The minimum duration for projects is 12 months and the projected time should not exceed 36 months.
- Budget requests cannot exceed 20,000 USD.
- All other application criteria, procedures and deadlines as outlined in this document are to be respected.

Applicant Criteria:

- The Principal Investigator (project leader) and all listed co-applicants/co-investigators must be ISN members. Different membership types are available; please go to <https://www.theisn.org/membership/become-a-member>
- Applicants should be active in/for nationally recognized institutions.
- The Principal Investigator should be based in the LMIC where the project is taking place (see section below on criteria for collaborative projects).

Criteria for Collaborative Projects between Different Countries

The program's main goal is to build research capacity in low- and middle-income countries (LMIC). Collaborative applications between two institutions from an LMIC and a high income country (HIC) are of course welcomed but applications should clearly demonstrate the key role and benefits in regards to the LMIC.

Therefore collaborative applications are to respect the following:

- Projects should be as locally led and managed as possible in the LMIC.
- The Principal Investigator (PI), as listed in the application and program documents, should be based in the LMIC where the project is taking place. The collaborators/co-investigators can be located in a high income country (HIC).
- The PI's exact role needs to be elucidated by detailing the specific activities that justify this role, including grant preparation, project conception and design, study execution,

manuscript/abstract/presentation preparation and authorship. They should also be the primary liaison with ISN (exceptions can be made if language is an issue).

- The application should clearly demonstrate that the LMIC applicants will derive career benefit from doing this study and that the project will benefit citizens and scientists in the LMIC.
- The funds should be held in an institution in the LMIC and should be used for research rather than intercontinental travel, and the HIC investigators/institution should contribute co-funding if possible to demonstrate their commitment to the collaboration.

Application Steps

Step 1- Send Proposal to the Regional Coordinator and obtain letter of approval

Applicants must send their proposals to the ISN Regional Coordinators at least one month before the final submission deadline. We recommend the proposal already be in the format (or contain the content of) the application template as provided in the Annexes.

APRIL 1: send proposal to regional coordinator/ **MAY 1:** Online submission of application
SEPT. 1: send proposal to regional coordinator/ **OCT. 1:** Online submission of application

The Regional Coordinators are appointed to coordinate and survey the activities of the prevention programs on a regional level. The regional coordinator conducts a first review of the proposal to make sure the topic is suitable, that the application is of a sufficiently competitive quality and may make recommendations for improvements prior to providing the applicant with a letter of approval. Applications cannot be submitted without this letter of approval.

The updated list of regional coordinators is available on our website:
<http://cr.theisn.org/res/p/who-to-contact/>

Step 2- Register and Fill-out the Online Application

The program can only accept applications that are submitted via the dedicated ONLINE APPLICATION SITE: <http://cr.theisn.org>
This site is run on a platform named FluidReview.

The online system is opened up for welcoming new applications approximately 3 months prior the final application deadline. Meaning:

- As of JULY for the October 1st deadline
- As of FEBRUARY for the May 1st deadline

If you have never before had an account in one of ISN's FluidReview sites (each ISN program manages its applications via this platform) you will need to first SIGN-UP and create an account on the right hand side of the screen (use the 'Need and account' button).

Please note that the application site (<http://cr.theisn.org>) is separate to the ISN membership portal and does therefore not recognize your ISN membership password. A separate password is required. Once you have signed-up, you will be able to use the Sign-In fields (email & password) when you want to access your account and application page.

The platform enables you to access your project page, fill out information and save it until you access it next. This means you do not need to finalize your application all in one go, but you can add to it and edit it as necessary before you actually submit it.

The content of the application and requirements are described in the below section 'Application Guidelines'.

Step 2- Submit your online application by the deadline

Once all fields have been completed and all required additional documents have been attached you will see a 'Complete' notification in your main project page. Only then will you be able to press the 'Submit' button; you will receive a system confirmation of your submission.

Please note that you will not be able to edit anything once it has been submitted. The Program staff may get back to you if something needs to be corrected or clarified; if that is the case you will be able to re-access your application, do the necessary and resubmit it.

Note about resubmitting a previously unsuccessful application: projects that were unsuccessful in a previous round can be resubmitted (maximum 2 resubmissions are permitted). In this case, the feedback that was provided by the review committee (if any) for the previous application and the comments provided by the regional coordinator must be adequately addressed. The proposal will again need to be submitted to the regional coordinator for their assessment and letter of approval (by the indicated deadlines).

Application Guidelines

The project application must be prepared based on the application template attached to these guidelines (Annex A). The applicant must apply in English. Only online applications will be accepted and attachments should be electronic files (Word, Excel, etc.; no handwritten documents!)

The application should be completed as carefully and as clearly as possible so that it can be assessed properly. The proposal must provide detailed rationale, aims, and methodology. The applicant should be precise and provide enough details to ensure the application is clear - particularly as to how the aims of the project will be achieved; the benefit that will flow from it; whether the proposal is novel, feasible and the budget justified; and its relevance to the program's objectives.

Content of Application

For a complete and eligible application, you will need to submit/prepare:

- Regional coordinator's letter of approval as described above (as an attachment)
- Concept summary (maximum 0.5 pages)
- Project description (maximum 6 pages), including Specific aims, background and rationale, methods, research team, institutional environment, significance (as an attachment)
- Timelines (Gantt chart) (as an attachment)
- Relevant references
- Detailed budget (as an attachment)
- Patient Information Sheet and Informed Consent Form (as an attachment)

Templates are provided in Annex.

Duration of Proposed Project

The minimum duration is 12 months and the projected time should not exceed 36 months.

Budget Request

A detailed budget is required, preferably in Excel format so that the budget breakdown per type of budget item can be assessed (Please see Annex B for a *rough* example). The maximum fund available for a particular grant is US \$20,000 (per project application regardless of its duration! Not annually, per project).

ISN reserves the right to award less than the requested amount based on the results of the Committee's review. Given the limited resources, the grant is not intended to cover all the proposed budget of a given awarded project but merely to provide significant start up support.

If the project's expected costs exceed the maximum ISN funding of US \$20,000, the proposal must clearly explain how the project is to be accomplished via co-funding from another source. Applications that make vague statements about how the shortfall will be obtained are unlikely to be funded.

ISN research grants may not be used to support the salary of investigators, but only for project support. Nevertheless, the ISN Clinical Research Committee is aware that the human resources (project coordinator, doctors, network administrators, nurses and technicians) may have to take part-time or full-time leave from their institutions to participate to the prevention project. In this case, the proposed budget may include also payment for such people just related to the time of their involvement in the project. This should be clearly specified in the budget by the applicant. However, the ISN Clinical Research Committee encourages the applicant's institution to consider these prevention or research programs as part of routine clinical practice and community service and to make any effort to continue the economic support of its employers (doctors, nurses, technicians, health workers) during any time period spent on the project as full time staff.

Budget items related to costs such as intercontinental travel, congress registration, and accommodation are not favourably regarded.

The program's overall budget for the funding of projects is established every year by the ISN-Program Clinical Research Committee according to the annual fund assigned to the Committee by the ISN Council. Any changes in that overall budget will affect the number of projects funded.

Please see the section on 'Further financial considerations' in regards to extensions and budgets usage/allocation of ongoing and finalized projects.

Informed consent document and ethics

ISN recognizes the limitation of human study committees in developing countries. Nevertheless, the ISN Clinical Research Committee requires that the applications - which involve human studies - be reviewed and approved by whatever the local equivalent of a human subject/Ethics committee is. Should this local committee not be available, the applicant must state that the ISN and the Review Committee will work to insure that all research and data collection is conducted consistent with established guidelines for human studies, including informed consent and privacy protection.

An **informed consent document** must be submitted; it is to include a statement that the data collected will insure the privacy rights of individual subjects. This document needs to be provided in English (i.e. a translation) as well as in the local language. The attachment to be uploaded online is to contain both language versions.

Evaluation and Selection Procedures

The Program staff receive notification of a submitted application. They register the submitted proposals with an identification number and check the application for completeness and eligibility; applicants who need to add or correct something will be contacted.

Once general preparations have been made, the Clinical Research Committee members

commence their review and scoring task. For each proposal, the Committee members provide an individual evaluation through a scoring system that addresses specific items, namely the description of the scientific project, measurability of the objectives, the organization, the overall feasibility and the budget. At the discretion of the committee, the appropriate Regional Coordinator may be contacted for their opinion as to importance, feasibility, novelty etc. All scores and rankings are gathered, stored and calculated by the online platform.

The Chair of Clinical Research Committee is responsible for summarizing the scores and deliberating the results with the committee members when necessary, for considering the budgetary implications and identifying sponsors when/if possible, and for confirming the awarded projects to the ISN staff.

The results are announced to successful and unsuccessful participants personally via email. The results can be expected between 2-3 months after the submission deadline has passed.

Unsuccessful applicants will be contacted by their Regional Coordinator who will provide them with the comments left for them by the reviewers; these could be helpful for those who wish to resubmit their proposal in the next round.

Successful applicants will be sent a letter of congratulations and an explanation of the next steps regarding payment and reporting formalities.

Procedures after Project Acceptance

The applicants will be asked to confirm their acceptance of the grant and to provide the estimated start date of their project. They will then need to access their online project page in order to fulfill certain formalities:

- Submit the payment request (transfer details and a US W8 tax declaration form, provided online)
- Submit information for being included in the ISN online world map.
- Submit a photograph.

Once a year, towards the end of the year, all applicants will be asked by email to submit a report of ongoing activities, results, publications/presentations and outcomes. This pertains to projects that are ongoing as well as those that have been finalized. For those who submitted their applications online (after 2015) the reports will also need to be submitted online. For those who submitted their projects before the existence of the online platform, a template will be provided.

The Program Chair personally reviews all reports and may request additional information in certain cases. The results/outcomes of all awarded projects are also reviewed periodically by the ISN Council.

The Principal Investigator/applicant is to acknowledge the support of the ISN Clinical Research Program in any publications derived from the awarded project. Projects that have been sponsored and/or co-funded by an ISN partnering society must also mention that

support in connection to any derived publications/presentations. A copy of the published paper(s) or abstract(s) presented to national/international Meetings dealing with the project are to be sent to the Program staff.

Budgetary Policies for Ongoing Projects

The program's overall budget for the funding of projects is established every year by the ISN-Program Clinical Research Committee according to the annual fund assigned to the Committee by the ISN Council. Any changes in that overall budget will affect the number of projects funded. The ISN Clinical Research Committee will be responsible for balancing the need to fund new projects every year, maintain the minimum necessary support for ongoing programs and limiting total funding to remain within available resources as approved by the Council.

The maximum fund available for a particular grant is US \$20,000. This fund is to cover the entirety of the submitted project proposal regardless of its duration in months; it is not an annual allocation. This means that if your project is, for example, 36 months in duration you will not be entitled to request more funds for the second and third year.

If your project has passed its planned duration – as initially proposed and approved – and you have remaining funds, you can use the remainder for an extension of your existing project, as opposed to resubmitting a new application. This is to be formally requested and is dependent on the review and approval of the Chair. Please send us a 1 page summary including: what you plan to study and the costs involved (budget breakdown of usage of remaining funds)

If your project has passed its planned duration – as initially proposed and approved – and has used up the allocated funds, but still needs some time and funds in order for it to be successfully finalized and reach its objectives, you can resubmit an application in a subsequent round provided the grand total of all allocated funds over the different application rounds does not surpass 20.000 USD. So if your project, as described in the initial plan, has terminated and received a grant of 15.000 USD, you can re-apply for a further 5.000 USD. This allocation/acceptance will be dependent on the submitted application and review of the extended project proposal; the process remains competitive and a positive outcome is not guaranteed.

Please note that all grant holders will need to submit a detailed report each year in order to inform the chair of its progress (and/or obstacles). Along with the report a detailed breakdown of the used funds will need to be provided.

Unused funds should be transferred back to the ISN. After having submitted your final report along with the 'budget usage breakdown' section, you can send us a quick email to research@theisn.org to let us know about the intent to wire us back the funds. You can let us know at that time if you require an official invoice. The instructions for USD wire/transfers are listed below:

To: International Society of Nephrology

Reference: CRP – (short) name of your project – country – your name
Bank Name: Wells Fargo
Bank Address: 1753 Pinnacle Drive
McLean, VA 22102, USA
Phone: +1-703-760-5980
Account Name: International Society of Nephrology
Account number: 2000028807102
Routing/ABA Transit Number: 121000248
Swift Code: WFBIUS6S



ANNEX A – Application Template

ISN CLINICAL RESEARCH PROPOSAL

Section A: *General Project Information (1 page)*

1. **Country/Region:**
2. **Project title:**
3. **Name and address of the coordinating Institution (Applicant)**
Legal name:
Address:
Head of the Institute/Department:
4. **Name of the principal investigator/ local coordinator of the project**
Full Name:
Position:
Contact Address
Email:
Phone no:
Fax no:
ISN membership number:
5. **Duration of the project:**
6. **Co-Investigators/ Collaborators**
Name
Role in project
7. **Name of the Regional Coordinator who was consulted about the project and their letter of approval (As an attachment)**

Section B: **Concept summary (maximum 0.5 pages):**

What (intervention/exposure, outcome) will this project study, why (rationale), in whom (population), how (what design will be used), over how long (duration) and what impact will it have (significance)?

Section C: **Project description (As an attachment) (maximum 6 pages, single spaced)**

1. **Specific aims of the program (approximately 0.5 pages):** What are the objectives of your project? Please provide 1-4 objectives; fewer is better. Each objective should be specific, measurable and linked to a hypothesis. See Appendix for examples.
2. **Background and rationale (approximately 1 page):** What is the previous work that has led you to contemplate this study? Why is this project important? Why is it important for the investigator's country/region? Why is this work novel or how will it extend what has already been done? How will the results be used? What is the budget requested in USD?
3. **Methods (approximately 2-3 pages):** Provide a detailed description of how the work will be done. Try to address the following as appropriate:
 - **Primary and secondary outcomes:** What outcomes will you study? How will these outcomes be defined? Who will assess them and how?

- **Inclusion criteria/exclusion criteria:** who will be eligible and ineligible to participate, and why?
 - **Confounders/covariates:** how will you account for the possibility of confounding and bias? If there are potential confounders, how will these be defined/measured and how will you account for them in analysis?
 - **Recruitment/sampling method; sample size calculation:** how will you identify participants? How many participants do you need to make the study worthwhile and is this feasible?
 - **Statistical methods:** how will you analyze the data? Do you have the skills to do the analysis yourself, or will you involve a statistician colleague?
 - **Ethical considerations:** have you obtained/will you obtain ethics approval for this study? Are there any other ethical considerations to be addressed?
 - **Knowledge translation:** who needs to know about the results of your study, and how will you ensure that they are aware of the findings once the study is finished?
4. **Research team (approximately 0.5 pages):** who are the members of your team, why are their qualifications/experience relevant for this study? What will each member of the team do? Does the team have the necessary skills and experience to do the work?
 5. **Institutional environment (approximately 0.5 pages):** provide a few details about your institution, and why it is a suitable environment to do this work. Does it have the necessary facilities/patient population to do the work?
 6. **Significance (approximately 0.25 pages):** what do you expect to find, and how will this make a difference? What impact will it have scientifically, or to healthcare in your country/region? What are the next steps once this study is finished?

Section D: Timelines (Gantt chart) (As an attachment)

Section E: Relevant references

Section F: Detailed budget in local currency and USD (As an attachment): What funds do you need and why? Is the budget sufficient to complete the project? If not, where will additional funds come from? How did you estimate the costs?

Section G: Patient Information Sheet and Informed Consent Form (As an attachment)

Appendix: Examples of “Specific Aims”

Devising appropriate specific aims is the most important part of formulating a research project. Although specific aims will fit on half a page (or less) it may take more than a dozen rounds of revision before they are finalized. Read and reread your specific aim, ensuring that they are specific and clear. Each aim should usually be followed by a hypothesis, although this may not be necessary for purely descriptive aims.

Example of a vague (inappropriate) specific aim:

Study whether ACE inhibitors improve outcomes in CKD patients.

Example of a better specific aim:

Use a two parallel group randomized trial to compare the effect of lisinopril 20mg daily with placebo for progression to dialysis-dependent kidney failure over 48 months in Martian adults with non-proteinuric polycystic kidney disease and baseline eGFR 30-59.9 ml/min/1.73 m².

Comment 1: there is a balance between specificity and clarity. For example, in the aim above, the terms "adult" and "non-proteinuric" are not defined. If these definitions are very important, they could be included in parentheses within the aim. If they are less important, they could be defined only in the methods. This requires a judgment and there may be no right or wrong answer.

Comment 2: ideally, specific aims will be followed by a hypothesis as below:

Use a two parallel group randomized trial to compare the effect of lisinopril 20mg daily with placebo for progression to dialysis-dependent kidney failure over 48 months in Martian adults with non-proteinuric polycystic kidney disease and baseline eGFR 30-59.9 ml/min/1.73 m². *We hypothesize that lisinopril will significantly reduce the rate of progression to kidney failure, compared with placebo.*

ANNEX B – Example of Budget Breakdown/Request

Please note, this is just an example should you find it necessary to see one. The items and how they are categorized are to be listed in terms of each project's needs.

Budget Item	Unit Cost	Number of Items	Total Cost (currency?)
Laboratory tests			
Serum	14.0	2000	9,03
Cholesterol	20.0	2000	4,3
Plasma glucose	15.0	2000	3,225
Urine uric acid	9.0	2000	1,935
Cortisol	77.0	300	7,7
Serum TSH	55.0	300	5,5
Equipment			
Weighing scales	100	2	200
Printer	60	1	60
Miscellaneous			
Data Entry Personnel	400	2	800
Statistician	500	1	500
Syringes	2	2000	4000
Stationery (1 pack A4 sheets)	10	6	60
Ink	7	10	70
Petrol /L.	0,52	300	156
		Total (local currency?)	5877,69
		Total (\$ USD)	8395,4

ANNEX C – Informed Consent

(Standard form)

Object:

Title of the project

I understood the purpose of the study as well as the potential benefits and risks of participating to the study. I had the opportunity to ask questions and my questions have been answered. I hereby give my Informed Consent to participate to this study. I have been given a copy of this Informed Consent Form.

I understand that, by signing this Informed Consent, I authorize access to my medical records to the monitor(s) and the auditors(s), and possibly to members of the Ethical Committees or Health Authorities, for verification of clinical study procedures and/or data.

I also realize that the information obtained from this study, including the results of all tests upon myself, will be held in both computerized and paper filing systems, although these will not identify me by name.

I understand that I am free to withdraw from the study:

- at any time
- without having to give a reason for withdrawing
- and without affecting my future medical care

Subject/Patient's signature:

Date:

Patient's name:

I, the undersigned, have fully explained the relevant details of this study to the subject/patient named above to consent.

Doctor's signature:

Doctor's name:

A copy of the signed Informed Consent form must be given to the subject/patient